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D5.1 Selected health technology assessments in mHealth

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Abstract

This reports details two health technology assessments of mHealth case studies. It follows the core EUnetHTA Core Model methodology.

Document History

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List of Participants

No.	Participant organisation name	Participant short name	Country
1	Atos Research and Innovation	ATOS	ES
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Contents

Executive Summary

This report assesses two case studies in mHealth utilising the EuNet Core HTA model as a methodology. The report demonstrates some of the difficulties in assessing, from a HTA perspective, all of the benefits as well as drawbacks of potential mHealth services, devices and technologies. These difficulties reflect the systemic changes in the delivery of healthcare which might accompany some mHealth deployments and the difficulties in assessing impact on 'wellness' and the prevention of further debilitation from chronic diseases as opposed to clinically measurably impacts on health. The EuNET Core HTA model addresses some of these difficulties by virtue of the fact that is a holistic multi-disciplinary approach to health technology assessment.

This assessment aims to validate key points as indicated in the roadmap for mHealth developed by the MovingLife project; however given that mHealth solutions are yet to be widely developed, deployed or implemented the assessment is limited in some ways. These limitations are primarily linked to what has been possible to assess effectively given the current and expected state of play with regards to mHealth technologies in the short term.

1 Target audiences

This report is targeted at a wide audience including clinical professionals with an interest in mHealth, policy actors involved in health-care, end-users and patient groups, technology producers and other stakeholders interested in the potential impacts of mHealth. The report also is targeted at those involved in health technology assessment, in particular in demonstrating some of the challenges involved in assessing mHealth as a specific category of technology in health-care delivery.

2 Introduction

The MovingLife project has demonstrated in its report on the current state of play and the evidence used in providing a roadmap for future implementation that mHealth devices, technologies and services are on the cusp of large scale deployments with wide ranging ramifications for healthcare practice and delivery in Europe. Adequate health technology assessment is and will be an important element of determining and measuring the potential positive benefits this trend will engender. As of now only limited evidence exists on the usage of mHealth devices in specific health contexts and as such use remains relatively recently many of the longer term implications of mHealth can be effectively assessed on the basis of their being a lack of evidence. It is certain that this will change with continued and growing use of mHealth devices and services over time. Currently however what mHealth devices do exist and are being implemented provide some evidence which can be used in an assessment of their potential impact and serve as a confirmation of elements of the roadmap produced by the MovingLife project. This report considers two healthcare contexts, chronic obstructive pulmonary disease and the management of diabetes, where products or devices exist. In order to remain neutral in terms of potentially recommending any one product and to be non-partisan the assessment in this report aggregates the functions and capabilities of various mHealth devices being offered within both of these contexts. While this approach means that there is no one specific device, offered by commercial or non-commercial developers of mHealth solutions, assessed in this report, the assessment of the variety of functions offered by each of these devices serves as a good indicator of how developments in mHealth will impact on healthcare delivery and practice in these two areas.

3 The EuNET HTA Core Model

The HTA core model provides a harmonised and systematic methodology for technology assessment in the health area[1]. The model provides a common language and framework and a set of methodological principles that addresses key issues in health technology assessment within Europe[2]. The MovingLife project decided to utilise the model representing as it does a uniform, best-practice and standardised approach for health technology assessment in Europe.

3.1 Overview

This section provides an overview of the process and elements contained in the EuNET HTA Core Model. It also provides commentary on some of the specific considerations that an assessment of mHealth services and technologies necessitates. While there are commonalities between eHealth and mHealth, with eHealth specific components a part of the model, mHealth engenders some specific considerations that are novel from the perspective of health technology assessment[3]. In particular the impacts of mHealth often go beyond what are primarily clinical effects due to the potential for technologies to redefine the meanings, practice and organisation of clinical space and care pathways[4].

3.2 Methodology

The key premise of the HTA Core model are assessment units located in domains of relevance to technology and health-care. These assessment units are comprised of domain-topic-issue. These issues in turn themselves are often framed as research questions addressed during the assessment of the technology and its impact on different domains in the health-care setting. Within the Core model there are nine domains. These nine domains also reflect the fundamental premise of the Core model in that it is a multidisciplinary approach to health technology assessment. The nine domains also allow for a versatile and wide-ranging assessment of technology[5].

In researching the assessment elements different methodological tools can be used dependent on the context, scale and objective of the HTA. These can include primary sources of research as well as reviews of secondary data relevant to the particular assessment element.

The nine domains of the Core model are listed and described below,

3.2.1 Health problem and current use of technology

This domain describes the health problems of the populations the technology is used for, the epidemiology, the burden of disease on individuals and the society caused by the health problem. It also provides the baseline description of the availability and patterns of use of the technology, and

[1] http://www.eunethta.eu/

[2] *Ibid.*

[3] Vital Wave Consultation. mHealth for Development (2009). The Opportunity of Mobile Technology for Healthcare in the Developing World. Washington, D.C. and Berkshire, UK: UN Foundation-Vodafone Foundation Partnership.

[4] *Ibid.*

[5] *Ibid.*

describes the alternatives and regulatory status of the technology. The MovingLife project in other deliverables, such as the Current state of play and the roadmap explored some aspects of the issues here. This assessment focuses on management of diabetes and mental health as the two health problems addressed by mHealth devices and services.

3.2.2 Description and technical characteristics of technology

This domain details and separates the technology in question from related technologies, and gives an overall understanding on functioning of the technology under assessment, including investments and information needed for use. A number of devices are emerging onto the market, or making the transition into widespread use in both of the health areas forming the assessment. The assessment however does not focus on any one device or technology but rather in aiming to be non-partisan aggregates functions from available devices to assess how mHealth technologies in general are addressing the health problems covered in the assessment.

3.2.3 Clinical effectiveness

This domain describes the efficacy or effectiveness of the technology in terms of health outcomes, function and patients' quality of life. As direct evidence from randomised controlled trials (RCT) is not available or sufficient in all assessments, there are also questions related to indirect measures, such as accuracy and change-in-management. As of yet most mHealth devices have not been subjected to RCTs, in part this is also due to the specific approach which mHealth devices are taking. In this sense for example the management of chronic diseases is as much about the reduction of the impact of conditions and preventing further clinical episodes as it is with improving clinical outcomes associated with conditions. It remains to be seen whether RCTs are an appropriate tool for measuring the effectiveness of mHealth technologies. A means of standardising more indirect measures may be seen as one key objective as mHealth technologies proliferate in healthcare settings.

3.2.4 Safety

This domain considers the direct and indirect harms due to the technology itself (e.g. invasiveness) or to the use of the technology (e.g. proper patient selection or learning curve), or to particular patient susceptibility (e.g. pregnancy). In addition to patient safety, the harms of the technology posed to the families and close ones of the patient, health care professionals, public and the environment, are considered. Given that mHealth is on the cusp of being utilised in healthcare settings and given the focus on patient empowerment in terms of how their conditions are managed and where there conditions are managed safety has the potential to be one key element in assessing these technologies. However there is limited empirical evidence thus far to analyse the longer term implications of for example patients reducing in/out patient visits and performing more of their own care in their own residential, social or workplace settings.

3.2.5 Costs and economic evaluation

This domain identifies, measures, values and compares the costs and outcomes of technologies being considered to inform value-for-money judgments about the intervention. The main aim is to provide information in order to improve decision-making in the health care sector regarding priority-setting between different health technologies. In all literature promoting and discussing mHealth the impacts on costs are seen as one of the fundamental positives that mHealth technologies and services can deliver, for patients, healthcare professionals and society. Given the current state of play there is a lack of evidence to demonstrate the long term implications of the use of mHealth technologies but some estimation can be made of reductions in costs associated with the two conditions examined in this assessment.

3.2.6 Ethical analysis

This domain considers prevalent social and moral norms and values relevant for the technology in question. Ethical questions are addressed both with regard to the technology itself and with regard to the consequences of implementing or not implementing a health technology. In addition, the moral and ethical issues inherent in the entire HTA process are identified and evaluated. mHealth like other innovative technologies in healthcare poses a number of ethical questions reflecting primarily how they alter the relationship between patient and healthcare professional and redefine the meaning of what constitutes the clinical space. While patient empowerment is often for example lauded as a positive goal for technology there have been a number of criticisms of what is focused on in terms of how patients are empowered. We discuss these in relation to the two health problems forming the basis of this assessment.

3.2.7 Organisational aspects

This domain focuses on the delivery models of the technology, resources, management and cultural issues within variety of stakeholders in the intra-and inter-organisational level and in health care system level. The assessment of the organisational issues is highly context-dependent because of the inherent complexities of the health care system and multiplicity of objectives. Proponents of mHealth as with impacts on economic issues see mHealth technologies and services having the potential to radically alter organisational aspects in healthcare delivery, practice and workflows. mHealth deployments represent a significant shift in the organisation of healthcare delivery but it is difficult to evaluate the impact of this given the long term nature of its impact.

3.2.8 Social aspects

This domain focuses on the patients' and his or her significant others' considerations, worries and experiences before, during and after the health technology has been put to use. It describes how the technology moulds and is moulded in diverse social arenas (hospitals, general practitioner, everyday life, homes, schools, and workplace), and what specific meanings people give to the technology. The implementation of mHealth technologies in healthcare settings can arguably be said to build on a number of significant changes in human societies over the last ten years. The proliferation and prevalence of devices, technologies and services that keep us connected, or online, 24/7 has arguably been one of the major societal trends during this period. Portability in terms of enhanced computer and network performance means that in most instances individuals are in possession of devices, such as smartphones, which often rival the power of desktop pcs and certainly surpasses the performance of desktop pcs which were common 10 years ago. It is this computing and network revolution which is the engine, driver and enabler of mHealth devices and services.

3.2.9 Legal analysis

This domain scrutinizes relevant legal sources in national or international legislation and conventions. It describes the implicit and explicit agreements of the manufacturer (or seller) and buyer of the technology. It includes questions on basic rights of patients, such as autonomy, informed consent, privacy and confidentiality, and legal requirements such as authorisation, guarantee, and regulation of market. The MovingLife project has already considered a wide range of legal issues engendered by

developments in mHealth which are set out in the report on the current state of play as well as the roadmap document.

3.3 Applying the Core Model to mHealth innovations

Applying the core model to mHealth creates a number of challenges. Firstly due to the fact that mHealth applications can potentially impact on a number of different points in a health-care system this means quantifying all possible benefits or drawbacks is difficult to do. Secondly most mHealth applications are focused on the management of chronic conditions, in these instances patients may not ever recover and the benefit of the mHealth solution is improved quality of life or reduction and prevention of more costly clinical events. These again pose methodological challenges in quantifying their effectiveness. Finally as evidenced by the work of the MovingLife project specific implementations of mHealth solutions are currently very limited in Europe meaning that there is lack of an evidence base to-date in analysing the impact of mHealth solutions and technologies on aspects of health-care. This report draws on the results of the simulation conducted as part of WP5 as well as available statistics on a recently FDA approved mHealth solution for managing diabetes.

4 Case study 1: Cross-border care and pulmonary disease

The first case study covered in this report follows the simulation developed and conducted within WP5 of the MovingLife project in assessing the possible impact of a mHealth enabled system of delivering care to patients with pulmonary conditions. The simulation covers a scenario where an Italian woman is travelling for work in Denmark. During her stay she feels unwell and makes use of a mHealth device and service to receive treatment in Denmark. The full details of the storyline used in the simulation are set out in the simulation report.

The simulation addresses one of the core visions of how mHealth services and technologies can alter the provision of healthcare in Europe, namely simplifying and enabling a greater degree of cross-border care than is the case currently. In terms of conducting a health technology assessment the simulation scenario also however points to arguably one of the critical difficulties in performing such assessments effectively and accurately. This difficulty stems from the observation that part of the clinical routine is occurring outside of normal clinical spaces both in the patient's own country and the one in which they are travelling. Much of the implementation of mHealth services and technologies focus on this opening up of clinical spaces allowing patients greater freedoms about where their care takes place. The problem as a result from an assessment perspective is the lack of controlled clinical spaces in terms of identifying, evaluating and measuring the metrics by which health technologies can be assessed. In this assessment we attempt to highlight some of these problems and assess metrics that can be applicable in the case of mHealth devices and technologies.

4.1 Overview

Chronic obstructive pulmonary disease is a serious life-long condition which requires careful monitoring of a patient, environmental factors and medication to control and limit problems and

issues with the condition[6]. The mHealth technology and service evaluated in this assessment allows for a patient to record and transmit their data to healthcare professionals and also provides services whereby care for the patient can be given and accessed in countries other than their own.

4.2 Domains-Topics-Issues

4.2.1 Health problem and the current use of technology

Topic	Issue
Target condition	Which disease/condition is the technology intended for? **The device is used for the monitoring and management of chronic obstructive pulmonary disease.**
Utilisation	How is the technology going to be used? **The technology is used to monitor record and transmit patient health data to healthcare professionals. The technology also logs and records data for review in managing the condition.**
Target population	How many people belong to the target population? **4%-10% typical incidence within European countries**

Chronic obstructive pulmonary disease is an incurable but preventable and treatable condition[7]. Generally chronic obstructive pulmonary disease is the joint occurrence of two conditions, namely chronic bronchitis and emphysema[8]. The onset and progression of the condition leads to a narrowing of the airways with resulting constriction and difficulty in breathing for sufferers. The condition as a result can lead to restricted mobility and lowered ability to engage in normal everyday activities for those suffering from the condition. It is generally a late-onset disease with its occurrence usually after the age of 45[9]. In Europe chronic obstructive pulmonary disease was responsible for 4.1% of deaths in men and 2.4% of deaths annually in women[10].

[6] Rabe KF, Hurd S, Anzueto A et al. (2007). "Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease: GOLD Executive Summary". *Am. J. Respir. Crit. Care Med.* **176** (6): 532–55.

[7] *Ibid.*

[8] *Ibid.*

[9] Hanley ME. Chapter 2. The History & Physical Examination in Pulmonary Medicine. In: Hanley ME, Welsh CH, eds. CURRENT Diagnosis & Treatment in Pulmonary Medicine. New York: McGraw-Hill; 2003. http://www.accessmedicine.com/content.aspx?aID=575132

[10] http://www.european-lung-foundation.org/63-european-lung-foundation-elf-burden-in-europe.htm

Globally it is the 6th most common cause of death and in Europe is responsible for an estimated 200,000 to 300,000 deaths each year[11]. Variations in prevalence means between 4% and 10% of European citizens in different countries suffer from the condition. The prevalence and incidence of chronic obstructive pulmonary disease, unlike some other chronic conditions, is on the increase and it is estimated that by 2020 that it will be the 3rd most common cause of death worldwide[12]. Chronic obstructive pulmonary disease has a pronounced impact in terms of patients engaging in normal everyday activities such as work and other normal day to day activities. In Europe for all respiratory diseases chronic obstructive pulmonary disease is the leading reason for lost days in terms of productivity. These have been estimated to result in 43,000 working days lost per 100,000 people with a cost to the European economy of 28.5 billion euros[13]. Outside of these wider costs the costs to individuals as a result of an inability to participate in the labour force or engage in other normal social activities can have an emotional and psychological impact contributing to poorer overall quality of life[14].

A number of risk factors are associated with causing the condition and aggravating its effects in sufferers. Some of these are controllable by individuals whilst some are not. Controllable risk factors include smoking cessation while airborne pollutants and other environmental conditions can aggravate the condition in patients leading to attacks which further constrict and reduce normal breathing patterns in patients[15]. Management of the condition and the prevention of further complications due to the progression of the condition are usually a mixture of lifestyle changes and medication. The current use of technology in managing the condition is a mixture of devices which provide a reading indicating oxygen levels and degree of difficulty in breathing as well as devices in severe cases to deliver oxygen to patients in need of it[16]. Various types of medication are also used in the management of the condition with the main types being bronchodilators, corticosteroids and antibiotics[17]. Severe progression of the disease may in some instances lead to lung transplantation although this is restricted to end-stage progression of the condition[18].

4.2.2 Description and technical characteristics of technology

[11] *Ibid.*

[12] Mathers CD, Loncar D (November 2006). "Projections of Global Mortality and Burden of Disease from 2002 to 2030". *PLoS Med.* **3** (11): e442

[13] http://www.european-lung-foundation.org/63-european-lung-foundation-elf-burden-in-europe.htm

[14] Halbert RJ, Natoli JL, Gano A, Badamgarav E, Buist AS, Mannino DM (September 2006). "Global burden of COPD: systematic review and meta-analysis". *Eur. Respir. J.* **28** (3): 523–32. doi:10.1183/09031936.06.00124605. PMID 16611654.

[15] Rutgers SR, Postma DS, ten Hacken NH et al. (January 2000). "Ongoing airway inflammation in patients with COPD who do not currently smoke". *Thorax* **55** (1): 12–8. doi:10.1136/thorax.55.1.12. PMC 1745599. PMID 10607796.

[16] Kennedy SM, Chambers R, Du W, Dimich-Ward H (December 2007). "Environmental and occupational exposures: do they affect chronic obstructive pulmonary disease differently in women and men?". *Proceedings of the American Thoracic Society* **4** (8): 692–4. doi:10.1513/pats.200707-094SD. PMID 18073405.

[17] Simpson CR, Hippisley-Cox J, Sheikh A (2010). "Trends in the epidemiology of chronic obstructive pulmonary disease in England: a national study of 51 804 patients". *Brit J Gen Pract* **60** (576): 483–488. doi:10.3399/bjgp10X514729. PMC 2894402. PMID 20594429.

[18] *Ibid.*

Topic	Issue
Features of the technology	What is the technology? **The technology consists of a monitoring device, a tablet/smartphone with a dedicated application for recording entering data and networking technology giving the capacity to transmit data.**
Features of the technology	What is the aim in using the technology? **The aim in using the technology is to provide a more effective method of recording patient health data, a simplified measure of transmitting this data to healthcare professionals and assisting patients in managing their condition while they are travelling within European countries.**
Features of the technology	Who will apply and use this technology? **Patients under direction and the supervision of their responsible healthcare professional will use the technology. The criteria and decision on when to apply the technology is made by the patient's healthcare professional.**

The mHealth technology evaluated in this assessment consists of a number of interrelated components whose goal is to assist in the recording of health data by patients, allow for interactions with healthcare professionals and to provide assistance in the case of treatment being required in a different country from the patient's own. This latter service is however also useful for patients who travel within their own country and need to avail of medical treatment from other healthcare professionals not directly involved in the management of their condition.

The key elements of the technology are,

1. A device measuring important patient health data on the condition, such as oxygen levels, blood pressure and heart rate.

2. An online application which can be accessed by a device used by the patient, in this instance a tablet, but which can also be a smartphone or some other smart device with an interface and network communication capabilities.

3. The online application also interacts with a portal and repository of information on healthcare services available in different countries. The device can display relevant information and assist patients in securing access to care in different countries.

In performing these functions the mHealth technology examined here is dependent on critical external infrastructure, such as networks or internet access, to be able to function optimally for the patient and healthcare professionals involved in managing the condition.

4.2.3 Clinical effectiveness

Topic	Issue
Mortality	What is the effect of the intervention/technology on overall mortality? **Untreated COPD and untreated attacks can lead to death. Advance warning of deterioration in the patient's condition can significantly enhance the prevention of these attacks.**
Mortality	What is the effect of the intervention on the mortality caused by the target disease/condition? **COPD is a chronic and incurable condition. Adherence to routine monitoring of the condition and adherence to medication when required results in effective management of the condition.**
Mortality	What is the effect of the intervention on the mortality caused by other factors than the target disease/condition? **COPD does not have any direct co-morbidities linked with it, progression of the disease leads to a deterioration in health for the patient with however major impacts on their ability to carry out daily activities. Proper use of the device effectively manages the condition and reduces the chances of this occurring.**

As an incurable but treatable condition effective management of chronic obstructive pulmonary disease is a vital aspect of care for patients suffering from it in order to ensure there is no further progression or complications in the condition. In this regards patient adherence to medication regime, routine monitoring of the condition, avoidance of irritants and lifestyle changes are complementary elements of care.

Progression of the condition can lead to serious complications, reduced mobility and eventually death yet with effective treatment the prognosis for most sufferers is good. Compliance with proscribed treatment and lifestyle changes represent the best possibility for preventing progression and further complications occurring for patients suffering from the condition.

In this respect the devices examined in this assessment provide useful, effective and easy to use tools to monitor the patient's condition, record health data for easy access and retrieval by healthcare professionals and provides advice and assistance to patients in need of medical care in their own country and in areas where they are unfamiliar with the available healthcare. The device does not impact on other aspects of treatment such as the effectiveness of medication. However the online application can be configured to assist in ensuring the compliance of patients with medication regimens, for example, providing reminders to the patient through their tablet/smartphone that medication should be taken at proscribed times.

4.2.4 Safety

Topic	Issue

Patient safety	What kinds of harms can the technology cause the patient? **The technology builds on existing devices used by patients to record and monitor their health data. The technology does not pose any significant risks. Some risks could occur due to failure or errors in technology but these remain low.**
Patient safety	Does the existence of harms affect the acceptability of the technology? **There are no significant harms associated with the technology which would impact or affect the acceptability of the technology amongst patients or healthcare professionals.**
Occupational safety	What kinds of occupational harms can occur through using the technology? **The technology is exclusively used by patients; healthcare professionals can access or receive data recorded by patients. As a result there are no observable occupational harms associated with the technology.**

As a device and service which builds on the existing model of care provided by healthcare professionals for patients in the management of chronic obstructive pulmonary disease there are no significant new risks associated with the technology.

Existing risks which might be exacerbated or compounded by utilising the mHealth technology include failures in the devices or services to work properly and therefore incorrect readings might be given to patients or to healthcare professionals. Other risks include patients not responding in the correct fashion to deterioration in their condition and overall health in light of the data being recorded by them. This latter risk though is offset by the fact that a worsening of the patient's condition in the case, as opposed to chronic conditions which may not have symptoms which patients are aware of such as hypertension, of chronic obstructive pulmonary disease has a number of visible and difficult to ignore symptoms due to restricted capacity for breathing.

4.2.5 Costs and economic evaluation

Topic	Issue
Resource utilisation	What types of resources are being utilised in delivering the assessed technology? **The technology consists of a monitoring device, a tablet/smartphone on which an application is provided to enter and record data. The technology also makes use of existing communication networks to transmit and store data as well as provide relevant information to the patient or healthcare professional. As a result resources are already existent and generally in use by the patient and no other significant resources which are new have to be utilised.**
Indirect costs	What is the impact of the technology on indirect costs?

	The technology has the potential to significantly impact on indirect costs, generally incurred by patients in treating attacks associated with a worsening of their condition.
Unit costs	What are the unit costs of the resources utilised in implementing the assessed technology? **Unit costs associated with the technology will vary often significantly from patient to patient. They will also vary depending on the particular context of the patient, i.e. if care is needed as is the case in the simulation in a different country.**

Chronic diseases have significant cost burdens for patients, healthcare professionals and healthcare systems in Europe. These are comprised of direct as well as indirect costs. In terms of future challenges facing European healthcare systems the rise in costs for the treatment of and management of chronic diseases is one of the most critical. Chronic obstructive pulmonary disease fits into this dynamic and is of particular concern given the reported continued increases in its prevalence and incidence rates.

The device evaluated in this assessment does not significantly impact on any of the core direct costs associated with managing the condition, such as for example the costs of medication. Some costs not included in the existing care model include the costs associated with having a device/smartphone to record data and access the online application. Other direct costs include a subscription or charge for access to the internet in order to access the online application and to transmit data or to receive data in terms of information on available healthcare resources in the area where the patient currently is.

The impact on indirect costs is where the technology and service, as well as other mHealth technologies in general, can have dramatic impacts in reducing the burden of chronic diseases for patients, healthcare professionals and healthcare systems. However the issue in measuring these costs is due to the long term nature of the savings to, for example, lost productivity that occurs due to effective management of the condition in patients.

4.2.6 Ethical analysis

Topic	Issue
Principal questions about the ethical aspects of technology	Is the technology a new, innovative mode of care, an add-on to or modification of a standard mode of care or a replacement of a standard? **The technology is an add-on and a modification of the standard mode of care for chronic obstructive pulmonary disease. The technology essentially allows for continuous care to be provided to the patient within their own country and when they are travelling in a different country.**
Principal questions about the ethical aspects of technology	Can the technology challenge religious, cultural or moral convictions or beliefs of some groups or change current social arrangements? **The technology does not challenge existing religious, cultural**

	or moral beliefs and convictions. The technology has to potential to alter some social arrangements in terms of how cross-border care is delivered, managed and utilised by patients.
Autonomy	Does the implementation or use of the technology challenge patient autonomy? **The technology does not present a challenge to patient autonomy in its implementation and use. Rather utilisation of the technology allows for a potential enhancement of the autonomy of the patient in empowering them in managing their care within their own spaces and allowing them increased mobility between countries due to being able to access care in different European countries.**

The technology examined in this assessment does not present new ethical risks in either its implantation or use by patients and healthcare professionals. However there are some ethical issues when the wider context of utilising the technology is taken into account. These however are not unique to the technology or to other mHealth services in general. Indeed challenges facing European healthcare delivery may also mean that these ethical problems will be increasingly faced and need addressing in traditional and existing care models.

One particular ethical issue is related to access to the technology and devices evaluated in this assessment. Rising healthcare costs in particular in relation to chronic diseases means that even currently in most European countries decisions need to be taken on the allocation of scarce and strained healthcare resources. In this particular example of utilising and implementing a mHealth device to manage chronic obstructive pulmonary disease the assumption is that the patient has purchased and procured the equipment using her own funds through the medium of private healthcare insurance.

However it is not clear whether the additional costs incurred in utilising the system can be borne by all individuals. While the predominant mode of funding for healthcare in Europe is generally a mixture of public and private funding policy decisions on how the cost of mHealth devices should be balanced between the two remain to be addressed. Given that the example utilised here is also focused on the issue of cross-border care questions of access are further compounded and raise a slight risk that the mHealth technology as detailed here would remain the purview of those who have the financial resources both to access the technology and be mobile in different European countries.

mHealth technologies are not the only technological innovation which engenders this question but given the centrality of access to healthcare as a core value of the European Union and its Member States mHealth arguably occupies a special place in terms of how questions on access need to be tackled.

4.2.7 Organisational aspects

Topic	Issue
Process	What kind of work-flow, participant flow and other processes are needed?

	The technology builds on the existing model of care for chronic obstructive pulmonary diseases. The novel alterations to the model of care are the feature of increased ability for patients to engage with healthcare professionals in light of their recording of their health data and allowing them access to care in different countries.
Process	What kind of involvement has to be mobilised for participants and important others? **Patients are expected in utilising the device to comply with their established surveillance regimes in monitoring their condition. Healthcare professionals have greater access to patient data. In the case of cross-border treatment the required agreement between healthcare providers for reimbursement and participation in healthcare coverage needs to be in place.**
Structure	How does centralisation or de-centralisation requirements influence the implementation of the technology? **As with other mHealth technologies and services decentralisation of healthcare provision is a fundamental feature. In this instance decentralisation is critical to the ability of patients to access cross-border healthcare in an effective, seamless and easy manner.**

The mHealth device evaluated here while building on the existing care model for the management of chronic obstructive pulmonary diseases has a number of potential impacts which can radically alter the provision of care and organisational workflows in Europe for dealing with cross-border care situations. While situations involving cross-border care do occur currently in Europe, more often than not for emergency and critical treatment, the mHealth technology envisaged here allows for easier treatment in the case of emergencies as well as more routine interventions.

The mHealth technology examined here provides novel, near real-time and the potential for continuous monitoring of a patient's condition by healthcare professionals. The reverse is also true in that the technology and device can provide more immediate, sustained and easy access to healthcare professionals by patients.

Efficiencies can be introduced as a result of the mHealth technology and service in the delivery of care for patients suffering from chronic obstructive pulmonary diseases at various levels of healthcare system organisations. This can be as a result of increasing access to patients and their data to provide more up-to-date and accurate information pertaining to decisions on their medication and compliance with lifestyle changes. The system can also alert patients to environmental conditions that they would need to pay attention to in order to avoid complications.

4.2.8 Social aspects

Topic	Issue

Major life areas	What kind of changes may the use of the technology generate in the individual's role in major life areas? **Key beneficial changes enabled by use of the mHealth technology in this instance is the continued ability of the patient to perform more of their own care at home and on the move, even in different countries.**
Individual	How do patients, citizens, important others using the technology react and act on the technology? **The mHealth technology builds on existing models of care and existing technology to provide and evolved model of care for chronic obstructive pulmonary disease.**
Communication	What is the knowledge and understanding of patients and citizens of the technology? **As the technology builds on existing models of care, patients are familiar with the usage and operation of the device. Some training is required in the use of the online application and in how to access information when outside of the country where they reside.**

The mHealth technology evaluated in this assessment is built upon widespread and dramatic changes in European society as a result of certain technological innovations and their resulting uptake in medical settings. As with the second case study examined in this report the proliferation of smartphones and other devices which can provide mobile access to the Internet and other network type communications is a principal driver and enabler of mHealth services and technologies.

As such mHealth can also be seen as an implementation of these wider societal innovations into healthcare delivery. For most patients there is already a substantial degree of familiarity in utilising the types of devices that are involved in mHealth. As such utilising the mHealth device in managing their condition should be relatively easy and necessitate only a short period of training in order to be aware of the various functions and operations of the device.

4.2.9 Legal analysis

Topic	Issue
Autonomy of the patient	Is the voluntary participation of patients guaranteed adequately? **Voluntary participation of patients is guaranteed, a decision to recommend the usage of the technology is made by responsible healthcare professionals in conjunction with patients. Normally a needs assessment is carried out where the patient has indicated that they travel a considerable amount within the European Union and elsewhere. Careful consideration in this respect is given to identifying which countries have reciprocal care agreements in place and which do not.**

Privacy of the patient	Do laws/rules require appropriate measures for securing patient data? **Cross-border provision of care will require adherence to a varied landscape in terms of how medical data is handled and processed.**
Equality in health-care	Is the technology subsidised by society? **In this instance it is assumed that society is not subsidising the technology, it is offered as a service provided and paid for by the patient's own private healthcare insurance. This avoids some problematic issues with cross-border reimbursement. However subsidised implementations of the technology and service in other countries where public reimbursement is involved will require consideration, especially in light of the Directive on cross-border care.**

Legal issues in the implementation of mHealth technologies have been addressed by the MovingLife project in other deliverables such as the report on the current state of play and the roadmap for the implementation of mHealth in Europe. The technology evaluated in this assessment points towards the crux of some of the more problematic legal impacts of the implementation of mHealth services and technologies in the provision of healthcare services. In the main these are centred on issues of reimbursement for healthcare services provided in different EU countries other than the patient's own as well as what are the responsibilities for healthcare professionals in providing treatment to patients from different countries. Another key legal issue relates to how health data is accessed and processed by healthcare professionals in countries different to the patient's own.

4.3 Conclusion

The mHealth technology as implemented and described in the scenario generates a number of positive benefits for patients with chronic obstructive pulmonary diseases. In particular the device and service evaluated in this assessment contributes to allowing patients with the condition to continue to be mobile and feel secure in respect of their condition needing treatment or attention from healthcare professionals in different countries.

5 Case study 2: Diabetes in the UK

The second case study for this report is the potential application of a mHealth device into care and service provision for patients with Type II diabetes in the UK. A number of devices are beginning to come to market and this report examines one on the basis of its reported functions and uses in managing Type II diabetes.

5.1 Overview

Diabetes is one of fastest growing chronic diseases affecting the UK population. Adult-onset Type II diabetes' rapid growth in incidence rates in the UK (and elsewhere) has been linked with the profound lifestyle changes in society over the last 30 years. Increases in sugary and fatty foods as a proportion of overall diet, increased sedentary lifestyles with reductions in exercise and increases in life-expectancy have all been identified as contributors to the increased prevalence of the disease. It is

an incurable condition, is associated with other co-morbidities and without proper management leads to further health-complications and progression of the disease to the detriment of patients and health-care systems.

Effective management of diabetes is seen currently as comprising medication, in the form of insulin, and lifestyle changes to halt the progression of the condition. Effective management includes then surveillance and monitoring of the patient's condition by medical professionals and self-management by the patient in attempting to adhere to changing lifestyle patterns. This combination of clinical and personal needs has been identified by a number of companies developing mHealth technologies as one of the key areas for innovation and service delivery. As a result, the management and treatment of diabetes is one area where devices are already coming to market or are in the advanced stages of technological and commercial development.

5.2 Domains-Topics-Issues

5.2.1 Health problem and the current use of technology

Topic	Issue
Target condition	Which disease/condition is the technology intended for? **Adult-onset Type II diabetes**
Utilisation	How is the technology going to be used? **Remote health monitoring of patient (insulin levels) and adherence to lifestyle changes**
Target population	How many people belong to the target population? **2.6 million**

Type II diabetes occurs when the body is unable to produce sufficient levels of insulin to regulate normal levels of glucose in the individual[19]. In 2009 2.6 million people in the UK were diagnosed with Type II diabetes or around 5% of the population, in 2013 this had reached 3 million people[20]. The estimates are that by 2025 this will have increased to 4 million people with Type II diabetes living in the UK[21].

Type II diabetes is typically late-onset, affecting those over the age of 40 more, in 2006 almost 42% of those with the condition were over the age of 40, with 25% of sufferers over the age of 65.

[19] http://www.diabetes.org.uk/Guide-to-diabetes/Introduction-to-diabetes/What_is_diabetes/What-is-Type-2-diabetes/

[20] BBC News, '*Diabetes cases in UK hit high of 3 million people*', http://www.bbc.co.uk/news/health-21630812

[21] *Ibid.*

However increased prevalence rates amongst those under the age of 40 have been increasing over the last decade. Rates are slightly higher amongst men[22].

The strongest causative factor for the onset of Type II diabetes is obesity[23]. Given that in 2010 61.9% of women and 65.7% of men were classified as overweight or obese the increased prevalence and the risk of further dramatic expansions in the incidence of Type II diabetes can be seen. Rates of obesity in children are similarly problematic with 25% of children classified as overweight or obese by the time of their entry into the school system in England between the ages of 4 and 5[24].

Type II diabetes can be successfully managed but when not managed the progression of the disease can lead to serious health complications for patients. These include risks of cardiovascular disease, amputations; particularly of feet and lower legs, kidney disease, stroke, blindness, nerve damage and premature mortality. For patients there are significant financial burdens, reduced mobility and lower overall quality of life as the disease progresses, either through non-adherence to medication regimes and poor compliance with required lifestyle changes.

The cost to the National Health Service in the UK of diabetes is substantial and growing. In 2010 it was estimated that 10% of the total health budget was spent on diabetes and related co-morbidities. This represents a figure of roughly £9 billion.

The technology assessed here is a mHealth solution which provides remote monitoring of key health indicators for adults with late onset Type II diabetes. These indicators include insulin levels, self-reported by patients, data on the patient's weight and blood pressure. The second function of the system is to assist the patient in complying with lifestyle changes. These include goal-setting for exercise, changes to diet and reductions in other behaviours, such as smoking or drinking alcohol which would impact on the patient. This function of the device involves two-way communications between the patient and health-care professionals through the device.

5.2.2 Description and technical characteristics of technology

Topic	Issue
Features of the technology	What is the technology? **The technology is a set of sensors monitoring health data such as blood pressure. The device also has an interface where the patient can input other data. The interface can display messages and alerts and display data for the patient. The device can communicate with devices used by health-care professionals and transmit patient data.**
Features of the technology	What is the aim in using the technology? **Provide reliable monitoring of and data on the health status of patients. Assist patients in complying with lifestyle**

[22] Estimation of primary care treatment costs and treatment efficacy for people with Type 1 and Type 2 diabetes in the United Kingdom from 1997 to 2007*CJ Currie, EAM Gale, CD Poole - Diabetic Medicine, 2010

[23] *Ibid.*

[24] *Ibid.*

	changes.
Features of the technology	Who will apply and use this technology? **Patients and health-care professionals will apply and use the technology.**

A number of mHealth devices and systems are currently being implemented in assisting in the treatment and management of Type II diabetes. All offer roughly comparable functions in assisting in the management of diabetes which is reflected in the characteristics of the device described in this assessment.

The mHealth device assessed here has three key components.

- Sensors worn by the patient which communicate with the device hub, these provide monitoring of key health-indicators such as blood pressure, heart rate etc. Monitoring is episodic on a timeline determined by health-care professionals to suit the particular circumstances of the patient.

- An interface into which patients can enter data, such as insulin levels. The interface also provides alerts, information and other reminders in assisting the patient to adhere to lifestyle changes. The interface also allows communication between the patient and health-care professionals.

- Data storage and network communication, to share data between the patient's devices and the central system operated by the health-care professional or provider.

As the NHS is free at the point of care the device is given to patients, where appropriate on the determination of health-care professionals. Familiarisation and training with the device for patients is provided by health-care professionals.

5.2.3 Clinical effectiveness

Topic	Issue
Mortality	What is the effect of the intervention/technology on overall mortality? **The technology aims to reduce mortality by adherence and compliance with treatment regimens and lifestyle changes. The technology in this regards is dependent on proper use, motivation and active patient interaction with the technology and clinical professionals.**
Mortality	What is the effect of the intervention on the mortality caused by the target disease/condition? **Type II diabetes is an incurable condition but one which the symptoms and complications from the condition can be effectively managed. Effective management is down to adherence to medication and lifestyle changes on the part of the patient. By doing so patients with the condition can significantly enhance the duration and quality of their life.**

	Untreated diabetes or non-compliance with medication and lifestyle changes leads to death.
Mortality	What is the effect of the intervention on the mortality caused by other factors than the target disease/condition? **Patients with Type II diabetes, particularly where there is no or poor compliance with medication and lifestyle changes is linked with a number of co-morbidities.**

mHealth solutions for the management of diabetes are focused on the effective management of the disease, reductions in morbidities caused by the disease and reductions in co-morbidities associated with the disease. Diabetes itself is an incurable condition but effective treatment can prevent serious health complications, such as amputations, and significantly reduce mortality rates ascribed to the disease.

An important impact of mHealth devices such as the one examined here is though the redefinition of the meaning of clinical spaces. In the case of diabetes this is though a logical evolution of how care and management of the condition has been treated. The majority of individuals with the advent of portable glucose level testing devices engage in a regimen of self-testing and communicate these results during visits and follow-ups with their healthcare professionals.

Simplifying and making communication between patients and healthcare professionals more easy in terms of relating health data and information contributes to a more robust surveillance regimen, both for patients and healthcare professionals involved in their care. The principal risks for most sufferers of diabetes are non-compliance with testing and medication and non-compliance with proscribed behavioural changes which halt the progression of the condition and the incidence of other problems as a result of this progression.

5.2.4 Safety

Topic	Issue
Patient safety	What kinds of harms can the technology cause the patient? **The mHealth device does not pose a risk to the patient in terms of its use. The device monitors and transmits data recorded by the patient to healthcare professionals.**
Patient safety	Does the existence of harms affect the acceptability of the technology? **There are no clinical harms posed in the use of the technology.**
Occupational safety	What kinds of occupational harms can occur through using the technology? **There are no occupational harms created by use of the technology by clinical and healthcare professions.**

Current mHealth solutions aiding in the management of Type II diabetes do not pose significant safety risks in most areas. In general perhaps the key safety issue for mHealth solutions aiming to aid

the management of diabetes arises from the onus on the patient to adhere to their own treatment and medication plans, for which the mHealth solution is intended as a supplemental set of tools to aid this for the patient.

The interface for the mHealth device is similar to commonly available and used devices such as smartphones and tablets. This ensures for most users of the device a level of familiarity with how the device should be used, how data should be entered and how any information pertaining to their condition can be generated from the device. Even so and in particular to serve those who are not familiar with these types of devices healthcare professionals are instructed before giving patients the devices to ensure that adequate training is given to patients on the device's proper usage.

Effective implementation of the mHealth device in the management of diabetes also necessitates that healthcare professionals be familiar with the operation of the device. Communication from the device can be configured to suit the needs of the patient and the preferences of the healthcare professional, for example the device can be configured to send SMS messages to key healthcare staff's mobile phones in the case of emergency through to a level where data is transmitted to a central server for review by healthcare professionals on a daily, weekly or monthly basis.

5.2.5 Costs and economic evaluation

Topic	Issue
Resource utilisation	What types of resources are being utilised in delivering the assessed technology? **The mHealth device utilises a number of resources but does so in a manner which differs significantly from traditional clinical technologies.**
Indirect costs	What is the impact of the technology on indirect costs? **A core benefit of the mHealth device is the reduction of indirect costs incurred by clinical organisations in the treatment of diabetes. Allowing patients to control and monitor their own condition and treatment outside of the clinical setting will reduce hospitalisations, out-patient or GP visits and also as a result reduce the indirect costs associated with these.**
Unit costs	What are the unit costs of the resources utilised in implementing the assessed technology? **As the mHealth device involves usage outside of controlled clinical settings, the actual unit costs of resources used can and do vary greatly between different clinical settings and different patient/healthcare professional usage.**

The impact of mHealth solutions on the costs associated with the prevalence and incidence of diabetes are one of the primary drivers of adoption and implementation of mHealth solutions. mHealth devices and services are seen as innovations which can drive down costs, increase efficiency and allow for greater control by patients over their own personal expenditure on healthcare. While in

the UK most healthcare is free at the point of delivery through NHS provision for this latter point an impact can still be seen through usage of the device by reducing the incidental costs, such as travel, associated with the management of their condition. Effectively measuring these costs is however difficult as it would require and investigation and data on individual patients, i.e. the locality of their healthcare professional versus where they reside and mode of transport and other variables related to the amount and nature of costs they incur for visits to their healthcare professionals.

A further complication in terms of assessing the economic impact of this mHealth device is that the focus of the technology is on the prevention of other costs associated with poor or non-management of diabetes which leads to other more costly conditions and costly interventions required to treat these conditions. Current estimates for these costs in the UK are substantial but combine difficult to quantify estimates such as losses due to for example lost productivity in the workplace as well as easier to quantify costs such as rates of amputation, other surgery and increased medication as a result of progression of the condition.

One important cost impact of the mHealth device used in the management of diabetes is purported impacts on labour costs in respect of time spent by healthcare professionals in managing individual patients. Key functions of the device examined in this assessment allow remote monitoring by healthcare professionals of health data provided by patients, as a result reducing time spent collecting such data through outpatient visits. This impact is considerably amplified when multiple patients utilising the device are taken into account. As such in terms of improving the numbers of patients that healthcare professionals can deal with quickly, effectively and more efficiently is a critical positive impact of the device in managing diabetes amongst groups of patients by healthcare professional teams.

5.2.6 Ethical analysis

Topic	Issue
Principal questions about the ethical aspects of technology	Is the technology a new, innovative mode of care, an add-on to or modification of a standard mode of care or a replacement of a standard? **The technology is an innovative use of existing technologies and represents a novel approach to how care is delivered for diabetes patients.**
Principal questions about the ethical aspects of technology	Can the technology challenge religious, cultural or moral convictions or beliefs of some groups or change current social arrangements? **The technology has the potential to alter approaches to delivering patient care, emphasising patient empowerment and autonomy in how their care is managed. The potential for rebalancing patient/physician relationships exists but represents a longer term potential social re-arrangement.**
Autonomy	Does the implementation or use of the technology challenge patient autonomy? **The technology does not challenge patient autonomy but more rather seeks to enhance patient autonomy by allowing**

	patients greater freedom and control in managing their care remotely with the assistance of health-care professionals.

mHealth solutions for the management of diabetes have an impact on a number of ethical issues, often in a transformative way due to the technology being an implementation whereby new clinical spaces and care pathways are created. Perhaps the critical ethical impact of mHealth is its focus on patient empowerment, which must be regarded as a double-edged sword, with more of the negative aspects potentially arising out of the manner in which the devices are seen and implemented within healthcare settings.

In terms of positive influences on patient empowerment perhaps the fundamental strengths of the device is its ability to allow patients more control over how and where the management of their condition takes place. Given that Type II diabetes is an incurable condition patients after diagnosis are faced with a lifelong challenge in ensuring that their health does not continue to deteriorate through a rigorous routine of monitoring health data pertinent to the condition, adherence to medication and compliance with behavioural changes.

In terms of a potential negative impact through the rubicon of patient empowerment necssitates consideration of some of the wider social and political contexts in UK healthcare delivery centred on the principle of personalisation and responsibility. These twin trends have seen an increasing onus being placed on patients to comply with what is 'expected' of them in the management of their own care. Controversial aspects of this include the refusal of treatment such as kidney or liver transplants for alcoholics, withholding of cardiovascular treatment for those who are obese and show no indications of reducing their weight or the refusal of some treatments to those who smoke.

5.2.7 Organisational aspects

Topic	Issue
Process	What kind of work-flow, participant flow and other processes are needed? **The mHealth device represents a reconfiguration of existing work-flow processes rather than a new form. In terms of participant-flows the device represents a novel form in the treatment and control of Type II diabetes.**
Process	What kind of involvement has to be mobilised for participants and important others? **Involvement by patients, healthcare providers as well as purchasers is central to the success of the mHealth device.**
Structure	How does centralisation or de-centralisation requirements influence the implementation of the technology? **De-centralisation of care pathways is the embodiment of the rationale for the implementation of the device in the management and care for patients with Type II diabetes.**

mHealth solutions have the potential to revolutionise aspects of care delivery and the flows of care pathways. The principal locus of this revolution is moving care outside of the hospital or clinical setting and moving parts of the responsibility for treatment and care onto individuals themselves and

the mHealth devices being used. In addition to this the connectivity aspects of the mHealth device offer new ways for patients to communicate with healthcare professionals and vice versa.

In the UK and within the NHS eHealth has penetrated organisations to a considerable degree although there are acknowledged variations between regions and different services within the UK and the NHS. As such most studies report a reasonably high level of familiarity amongst healthcare professionals in the NHS in the use of eHealth technologies and services in the delivery of care. Innovative eHealth solutions such as telehealth have also been trialled and piloted in both small scale and large scale settings.

mHealth while being an evolution constructed on the foundations of eHealth technologies and services does represent a departure however in a number of significant ways which can have major and minor impacts on organisational delivery of healthcare and organisational practice and workflows in the delivery of healthcare to UK patients.

5.2.8 Social aspects

Topic	Issue
Major life areas	What kind of changes may the use of the technology generate in the individual's role in major life areas? **The device allows patients to regulate their care in their own time and within their own spaces. Reducing for instance the number of visits to clinical settings will empower patients to achieve more normality in their day to day lives, whether through participation in employment or other social activities.**
Individual	How do patients, citizens, important others using the technology react and act on the technology? **Patients, citizens and important others are key to supporting the effective implementation of the mHealth device in the treatment and management of Type II diabetes.**
Communication	What is the knowledge and understanding of patients and citizens of the technology? **While mHealth is a new concept both for healthcare professionals, patients and citizens generally the technologies upon which is constructed is familiar to the majority of these in their everyday lives.**

Implementation of the mHealth device to manage diabetes will have a number of social impacts. Many of these complement existing changes in society in terms of the proliferation of new devices, connectivity, interactive services and the continued evolution of a networked society. Implementation of the mHealth device in the treatment of diabetes also represents a significant change in how care is delivered and managed for patients suffering from the disease. Currently patients with diabetes tend to spend a significant amount of time on outpatient visits to healthcare professionals, normally for routine check-ups. The device examined here can significantly reduce the amount and need for these visits by providing routine health data for healthcare professionals on a regular basis. This means as a

result that healthcare systems can devote more outpatient based resources for other conditions and diseases.

Perhaps one value characterised in the promotion of the device and for mHealth in general is the idea of patients being empowered to manage their own care where they wish to. Allowing patients to remain at home for longer and more often and to engage in daily activities while still complying with their monitoring and treatment can have significant positive societal benefits both for sufferers, significant others and other individuals in society more generally.

5.2.9 Legal analysis

Topic	Issue
Autonomy of the patient	Is the voluntary participation of patients guaranteed adequately? **The mHealth device is a voluntary service offered by healthcare professionals in consultation with patients in determining the best method of managing their diabetes.**
Privacy of the patient	Do laws/rules require appropriate measures for securing patient data? **As with other mHealth devices a number of important issues need to be addressed in terms of data collection, retention and analysis. While some issues are addressed some currently are in need of further revision to adequately deal with the issues posed by this and other mHealth devices.**
Equality in health-care	Is the technology subsidised by society? **Subsidising mHealth devices by society will depend on the particular contexts of healthcare funding in respective European countries.**

The MovingLife project has examined the current state of play with respect to mHealth and legal issues in the deliverable outlining the current state of play. Specific elements examined here include the assumption that the decision to use the device or not is taken by the patient in conjunction with a detailed needs assessment performed by competent healthcare professionals. As detailed by the MovingLife project in other deliverables existing data protection frameworks provide a framework for dealing with health data involved in the implementation of mHealth technologies but these will be configured in tandem with how national frameworks deal with the storage and process of health data. In the UK for example the NHS and local healthcare providers have developed their own guidelines and frameworks which often go further in terms of the protection of health information.

The NHS is also unique in Europe in terms of how healthcare services are provided and financed. Free at the point of the care is a core value since the establishment of the NHS in post-war Britain. As such in this assessment it is assumed that the cost of the device and service is borne by the NHS and is funded through general taxation which finances the NHS. This of course may not be the case in other European countries. It is also unclear currently how the NHS would approach reimbursement for mHealth services that are utilised by UK citizens in other European and non-European countries. While some treatment and medical services are reimbursed often decisions on whether this is allowed or not is devolved to the level of local NHS trusts. One assumption is that the NHS will sometime in

the future produce a set of guidelines and a framework for dealing with the issue of cross-border reimbursement of mHealth services.

5.3 Conclusion

The management of Type II diabetes (and Type I) is a health condition where mHealth technologies can excel in delivering better, more effective and more efficient care at reduced cost for healthcare providers, society and patients. The device builds on the existing care model and extends it in allowing the patient more control over where the management and treatment of their condition takes place.

6 Conclusions

mHealth devices for different diseases and conditions are at various stages of implementation, from prototype to market-entry. Outside of small pilot cases and demonstrations there is relatively small evidence base of current everyday usage to draw on in assessing the technologies within the various categories outlined in the Core model. In the near future this reasonably can be assumed will have changed with considerably wider scale implementation of mHealth devices and services.

One of the common themes for mHealth services and devices is their use in chronic, often incurable, diseases and conditions. These are conditions which require lifelong management through monitoring, medication and lifestyle changes. From a commercial perspective it is clear that innovation in these areas in the private sector is partly driven by the fact that these conditions are life-long, incurable and in need of continuous management by patients and healthcare professionals.

However given the immense challenges associated with the increased costs of these diseases for European healthcare systems then the potential for commercial benefits creates an opportunity for a triple-win, for patients, companies and healthcare systems in overcoming these challenges. However as other deliverables produced by the MovingLife project have indicated, achieving this triple-win, will require considered co-ordination between all relevant actors. Finally this assessment has indicated from the patient, healthcare professional, healthcare service through to society that mHealth technologies can delivery meaningful positive benefits. However realisation of these benefits likewise depends on the success of the co-ordination indicated above.